K120515

MAY 23 2012

5. 510(K) SUMMARY

Submitter's Name:	NeuroStructures, LLC
Submitter's Address:	63 Bovet Road, Suite 135 San Mateo, CA 94402
Submitter's Telephone:	800-352-6103
Contact Name:	John Stephani
Date Summary was Prepared:	02/16/2012
Trade or Proprietary Name:	Tempus™ Cervical Plate System
Common or Usual Name:	Spinal intervertebral body fixation orthosis
Classification:	Class II per 21 CFR §888.3060
Product Code:	KWQ
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Synthes CSLP Cervical Plate (K030866) Centerpulse Spine-Tech Trinica Select™ Anterior Cervical Plate System (K012305)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Tempus™ Cervical Plate System consists of screws and plates. Screws are available in a variety of diameter-length combinations. Plates are available in a variety of lengths to accommodate fusion procedures from one to five levels of the cervical spine. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The Tempus™ Plates include locking pins that cover the heads of the bone screws to reduce the potential for screw back-out. The locking pins come preassembled to the plate.

INDICATIONS FOR USE

The Tempus™ Cervical Plate System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

The indication for use for the Tempus™ Cervical Plate System is similar to that of the Centerpulse Spine-Tech Trinica Select™ Anterior Cervical Plate System (K012305) and similar to that of Synthes Spine Anterior CSLP System (K030866). The Synthes device does not include deformity in the indications for use but is similar in all other aspects. As the subject device has indications that are identical to one of

the predicate devices and similar to the second predicate device, the subject device does not introduce differences that are critical to the surgical use of the device.

TECHNICAL CHARACTERISTICS

The plates and screws are manufactured from titanium alloy meeting requirements of ASTM F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* Titanium alloy has a successful history of use in the spinal implant industry and use of it in these devices does not introduce any previously unaccepted patient risks. The Synthes CSLP plate is manufactured from commercially pure titanium, but the Trinica plate and Tempus™ plate are both manufactured from titanium alloy.

The Tempus™ Plates include locking pins that cover the heads of the bone screws to reduce the potential for screw back-out. The locking pins come preassembled to the plate. Both of the predicate devices have an interference to the screw head with the same intent. The Synthes CSLP plate has an automatic locking mechanism that collapses over the head of the screw. The Trinica™ Plate has a manual locking cover that is engaged over the screw head after the plate is in place, similar in technical characteristics to the locking pin that is utilized in the Tempus™ plate.

PERFORMANCE DATA

The Tempus™ Cervical Plate System has been tested in static axial compression bending, static torsion, and dynamic axial compression bending in accordance with *ASTM F1717–11 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.* The results of this non-clinical testing show that the Tempus™ Cervical Plate System can withstand the anticipated forces of the cervical spine and legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Tempus™ Cervical Plate System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Colorado Springs, Colorado 80918

MAY 23 2012

Re: K120515
Trade/Device Name: Tempus Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 16, 2012
Received: February 29, 2012

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120515

4. INDICATIONS FOR USE STATEMENT

Device Name: Tempus™ Cervical Plate System

The Tempus™ Cervical Plate System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120515